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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,536	04/15/2004	Hiroyuki Mano	251957US0	7145
22850	7590	12/22/2005	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			KAPUSHOC, STEPHEN THOMAS	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/824,536	MANO, HIROYUKI	
	<b>Examiner</b>	<b>Art Unit</b>	
	Stephen Kapushoc	1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1, 2, 3, and 5 in their entirety, and claims 6-8 in part as they depend from claim 1, drawn to methods for gene identification, classified in class 435, subclass 6.
  - II. Claim 4 in its entirety, claims 6-8 in part as they depend from claim 4, and claims 11 and 12 in their entirety, drawn to a methods for diagnosing disease, classifiable in class 435, subclass 7.1.
  - III. Claims 9 and 10 in part as they relate to an antibody, drawn to antibodies for diagnosing myelodysplastic syndrome, classifiable in class 530, subclass 350.
  - IV. Claims 9 and 10 in part as they relate to polynucleotides, drawn to polynucleotides for diagnosing myelodysplastic syndrome, classified in class 536, subclass 23.1.
  - V. Claims 13-16, drawn to methods for identifying compounds for treating myelodysplastic syndrome, classified in class 436, subclass 501.
  - VI. Claim 17, drawn to a drug for treating or preventing myelodysplastic syndrome, classifiable in class 424, subclass 130.1.

**Requirement for further restriction applicable to all groups**

Applicant shall further select a single myelodysplastic syndrome-specific gene from the group consisting of PIASy gene, LIM2 gene, NDUFV1 gene, and PNMA2 gene. Generic claims within each group will be treated as linking claims with respect to the requirement for restriction to a single gene.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods have different functions, specifically invention I is used for the identification of disease related genes, invention II is used to diagnose a disease state, and invention V is used to identify compounds suitable for disease treatment or prevention.
3. The method of Invention I is unrelated to products of inventions III, IV, and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of invention I (identifying disease related genes) neither recites nor requires the products of inventions III and IV (products for disease diagnosis) or the product of invention VI (drug for disease treatment).
4. Inventions III and IV are related to invention II as products and process of use. The inventions can be shown to be distinct if either or both of the following can be

shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products can be used for processes other than disease diagnosis. For example, the antibodies of invention III could be used for purification of proteins from cell lysates, and similarly the nucleic acids of invention IV could be used to affinity purify nucleic acids from native sources.

5. Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the diagnosis methods of invention II neither recite nor require the product of invention VI (a drug for treating or preventing disease).

6. The inventions of groups III and IV are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of invention IV is composed of nucleotides linked in phosphodiester bonds and arranged in space as a double helix. The antibody of invention III is also composed of amino acids linked in peptide bonds and arranged spatially in a specific tertiary structure that allows the antibody to specifically bind to particular regions, i.e. epitopes, of a polypeptide. Furthermore, the products of inventions III and IV have different modes of operation, for example, the polynucleotides of invention IV can be used in nucleic acid hybridization assays, whereas the antibody of invention III can be used in immunoassays. Consequently, the reagents, reaction conditions, and reaction

parameters required to make or use each invention are different. Therefore, the inventions of groups III and IV are patentably distinct from each other.

7. Inventions III and IV are unrelated to inventions V and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the products from disease diagnosis (inventions III and IV) are neither recited nor required for the method of invention V (methods to identify compounds for treatment), and have different functions than the product of invention VI (a drug for treating or preventing a disease).

8. Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the drug for treatment (invention VI) could be identified by methods other than those specifically detailed in invention V.

9. With regard to the requirement for further restriction among the myelodysplastic specific genes, each gene is patentably distinct because it is composed of a unique polynucleotide sequence. Because of the unique structure of each gene, a reference against one would not necessarily be a reference against any other, thus necessitating a separate search for each particularly named gene.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I - VI require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

  
Stephen Kapushoc  
Art Unit 1634

  
**JULIET C. SWITZER**  
**PRIMARY EXAMINER**